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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,038	03/11/2004	Paul T. Gardiner	11411/11502	6719

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EXAMINER	
CHOI, FRANK I	
ART UNIT	PAPER NUMBER
1616	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/799,038	GARDINER ET AL.	
	Examiner	Art Unit	
	FRANK I. CHOI	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *98,102-105 and 108-118* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *98,102-105 and 108-118* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20070829,20071030*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 102-105, 112-118 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 102 recites the phrase "The method of claim 98 comprising said at least one ingredient which increases nitric oxide production" which renders the claim indefinite as the language following "comprising" modifies the entire method and implies that the other components set forth in claim 98 are not necessary. Since only a specified component of the method set forth in claim 98 is being modified, claim 102 should only modify that component and not the entire method in claim 98. The Examiner suggest "The method of claim 98 wherein the at least one ingredient which increases nitric oxide production in the body is selected from the group consisting of . . . ." Claims 103-105, 112-118 are rejected also as they are dependent on claim 102 but do not correct the indefiniteness.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 98, 102-105,108-118 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tabor (US Pat. 6,482,448) in view of Hastings et al. (US 2001/0041187), Miller et al. (US

Pat. 6,019,999), Ostlund et al. (US Pat. 5,550,166), Shimizu et al. (US Pat. 6,004,926), Goldberg et al., and Goldberg.

Tabor discloses a dietary supplement which comprises a soy formulation and preferably comprising 70-90%, by weight, protein, 1-5%, by weight fat, and 1-25%, carbohydrate which may in the form of a powder or liquid form (Column 6, lines 15-46).

Hastings et al. discloses a performance-enhancing supplement in powder form which can be mixed with uice, water, milk or any other drinkable non-alcoholic beverage with the recommended daily serving being about 26 grams to about 78 grams in the which the major ingredient is soy protein (Paragraphs 0006, 0007). It is disclosed that the supplement contains an amino acid premix of l-leucine, l-glutamine, l-alanine, glycine, l-arginine, l-lysine and that glutamine promotes anabolic conditions in muscle cells, increase rate of protein and glycogen synthesis, and indirectly promotes muscle growth, that alanine is an important source of energy for muscle tissue and that arginine is essential for optimal muscle growth and tissue repair (Paragraphs 0008-0010). It is disclosed that the supplement contains fat in the form of medium chain triglycerides with improve the absorption of the amino acids (Paragraph 0012) It is disclosed that the dietary supplement should include carbohydrate which supplies an energy source (paragraph 0014). It is disclosed that L-carnitine is added as it has been shown that athletes who supplement their diet with the same convert fat to energy more efficiently (Paragraph 0017). It is disclosed that creatine is included in the dietary supplement to shorten the time necessary for the body to generate replacement creatine phosphate and significantly reduce muscle recovery time between short duration, high intensity activities (Paragraph 0016). It is disclosed that individuals on an intense physical training regiment will gain optimal results

at the higher levels of consumption whereas those on moderate or casual workout regimens will require less (Paragraph 0006).

Miller et al. discloses that for resistance-trained athletes the intake for protein should be approximately twice the normal RDI and that a preferred source of animal protein is dairy whey (column 1, lines 60-68, Column 2, line 1). A liposomal, ion-exchange whey protein is disclosed which is effective in increasing lean body mass, muscle mass with appropriate exercise and improving exercise performance (column 7, lines 46–60).

Ostlund et al. disclose that pinitol and derivatives and metabolites thereof are useful in nutritional composition for treating conditions associated insulin resistance including complications arising from athletic activity (Abstract). It is disclosed that inositol compounds improve insulin sensitivity (Columns 2, 3).

Shimizu et al. disclose a supplement containing protein, fat and carbohydrate which is ingested before, during and/or after exercise, particularly after the exercise immediately preceding a resting period, the protein is selectively taken up in the muscle tissue in the state where the process of protein assimilation is invigorated by the exercise, while the fat is combused as an energy source and consumed, with the resulting improvement in body composition contributing neatly to shape-up, body building, muscle increase and augmentation of the dynamic strength of muscles (Column 1, lines 55-68, Column 2, lines 1-64).

Goldberg et al. disclose that an increase in muscle weight reflects an increase in protein and results from greater protein synthesis and reduced protein breakdown and that hypertrophy leads to greater maximal tension development (Abstract).

Goldberg disclose that insulin reduces overall protein breakdown in skeletal muscle (Abstract).

The prior art discloses a dietary supplement which comprises a soy formulation and preferably comprising 70-90%, by weight, protein, 1-5%, by weight fat, and 1-25%, carbohydrate which may in the form of a powder or liquid form. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose a method of supplementing the diet of an athlete or supplementing the diet of a human by administering a dietary supplement which mimics or enhances insulin activity to enhance muscle size and strength.

However, the prior art amply suggests the same as the combined teachings of the prior art discloses amounts of protein and carbohydrate which encompass or overlap the claimed amounts, the incorporation of L-arginine, whey protein, glutamine, carnitine, alanine, creatine and compounds which mimic or enhance insulin activity such as pinitol, in compositions which can be in the form of powders which can be mixed with a diluent such as water, which can be administered to athletes or immediately after exercise. Further, the prior art discloses that muscle hypertrophy can lead to greater maximal tension development and that muscle size is a reflection of increased protein synthesis and decreased protein breakdown. Furthermore, it is disclosed that insulin reduces overall protein breakdown in skeletal muscle tissue. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the use of said composition would increase muscle mass and strength.

The examiner has duly considered the Applicant's arguments but deems them unpersuasive for the reasons set forth in the prior Office Action (6/28/2007) and the further reasons below.

The citation to website is not sufficient to provide evidence that whey protein is superior over soy protein. Objective evidence which must be factually supported by an appropriate affidavit or declaration to be of probative value includes evidence of unexpected results. See, for example, In re De Blauwe, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984) ("It is well settled that unexpected results must be established by factual evidence." "[A]ppellants have not presented any experimental data showing that prior heat-shrinkable articles split. Due to the absence of tests comparing appellant's heat shrinkable articles with those of the closest prior art, we conclude that appellant's assertions of unexpected results constitute mere argument."). "The reason for requiring evidence in declaration or affidavit form is to obtain the assurances that any statements or representations made are correct, as provided by 35 U.S.C. 25 and 18 U.S.C. 1001." Permitting a publication to substitute for expert testimony would circumvent the guarantees built into the statute. Ex parte Gray, 10 USPQ2d 1922, 1928 (Bd. Pat. App. & Inter. 1989).

The Applicant argues that whey protein alone is the closest prior art. However, the Applicant's claims do not even require that whey protein be present; for example, the source of protein can alternatively be whey peptides, milk protein, casein, albumins and soy (Claim 98). Further, as indicated above, the citation to a website is not sufficient to provide evidence that whey protein is closer prior art than soy protein. Furthermore, since the prior art also discloses that combination of the other claimed components, including creatine, in addition to soy protein, the Applicant has failed to establish that whey protein alone is the closest prior art.

The Applicant offers the Declaration of Dr. Marvin A. Heuer (6/15/2007) as evidence of synergistic activity. However, the declarant does not appear to have performed any comparative study with the closest prior art and merely cites to an abstract of another. An affidavit or

declaration under 37 CFR 1.132 must compare the claimed subject matter with the closest prior art to be effective to rebut a prima facie case of obviousness. In re Burckel, 592 F.2d 1175, 201 USPQ 67 (CCPA 1979). The test only compared Nitro-Tech® to whey protein and placebo, however, the claims encompass and claims and the prior art discloses the use of other proteins and other nutritional ingredients. A review of the Nitro-Tech® ingredient list clearly shows that the alleged evidence of unexpected activity is not commensurate in scope of the claims in that the claims considerably larger in scope than the tested composition. See In re Clemens, 622 F.2d 1029, 1036, 206 USPQ 289, 296 (CCPA 1980) (Claims were directed to a process for removing corrosion at "elevated temperatures" using a certain ion exchange resin (with the exception of claim 8 which recited a temperature in excess of 100C). Appellant demonstrated unexpected results via comparative tests with the prior art ion exchange resin at 110C and 130C. The court affirmed the rejection of claims 1-7 and 9-10 because the term "elevated temperatures" encompassed temperatures as low as 60C where the prior art ion exchange resin was known to perform well. The rejection of claim 8, directed to a temperature in excess of 100C, was reversed.). See also In re Peterson, 315 F.3d 1325, 1329-31, 65 USPQ2d 1379, 1382-85 (Fed. Cir. 2003) (data showing improved alloy strength with the addition of 2% rhenium did not evidence unexpected results for the entire claimed range of about 1-3% rhenium); In re Grasselli, 713 F.2d 731, 741, 218 USPQ 769, 777 (Fed. Cir. 1983) (Claims were directed to certain catalysts containing an alkali metal. Evidence presented to rebut an obviousness rejection compared catalysts containing sodium with the prior art. The court held this evidence insufficient to rebut the prima facie case because experiments limited to sodium were not commensurate in scope with the claims).

Further, the test does not show synergy. In order to show synergy one would have had to test the mimetic alone also in order to see if the effect of the combination was greater than the sum of the effect of mimetic alone and whey protein alone. However, since as indicated above, the tested composition contains an extensive number of other ingredients which may also effect muscle growth and strength, even this hypothetical test would not have been sufficient to show synergy which is commensurate in scope with the claims. Further, as indicated above, the Applicant has not shown that whey protein alone is the closest prior art. In any case, it is hardly unexpected that supplementation with combinations of compounds known in the art to increase muscle mass and/or strength would be better than a single compound.

Finally, there is no evidence that the declarant, Dr. Heuer, relied on full Burke et al. article cited in the abstract cited by the declaration. According to the Abstract, NITRO-TECH® was compared to pure whey protein and placebo. However, it is not clear that the product tested in the Burke et al. article is the same as NITRO-TECH® as the product label cited in the declaration clearly contains more ingredients than that listed in table 2 of the article. Further, Applicant's remarks do not appear to correctly indicate what was tested. According to the Applicant, whey protein, inositol and creatine was compared against whey protein and inositol and a placebo. However, the declaration indicates that NITRO-TECH® was compared against pure whey protein and a placebo. Whereas, the full Burke et al. article indicates that the whey/creatine supplement was more nitrogenous than the whey supplement because the whey/creatine supplement also contained inositol, arginine and N-acetyl-cysteine and that the whey/creatine supplement also contained American ginseng. The Burke et al. article crypitically indicates that all other ingredients were the same among supplements. It is unclear whether this means that the whey protein without creatine supplement also contained guar gum,

glucomannan, potassium phosaphte, folic acid, pyridoxine hydrochloride and alpha-tocopherol. However, it is clear that there appears to be some discrepancy between what was described as being tested between Applicant's remarks, the declaration and the full Burke et al. article. Further, the Burke et al. article clearly states that it was comparing the effect of whey protein, to whey protein and creatine and placebo on lean tissue mass and muscle strength after resistance training (Pages 349, 350). No conclusions or hypotheses were made as to the presence of insulin mimics or nitric oxide producers. A further limitation on the study done in Burke et al. is that it was only assumed that each subject consumed his required supplement four times per day (Pages 361, 362). As such, no conclusions can be made from the Burke et al. as to the effect that the presence of inositol, arginine, N-acetyl-cysteine and American ginseng had on muscle size and strength, much less their equivalents or broader catagories, such a insulin mimics or nitric oxide producers. Since claim 98 does not require the presence of whey protein or creatine or the other components in the NITRO-TECH® or even the shorter list set forth in Table 2 of the Burke et al. article which would have a beneficial effect on muscle growth and/or strength, it cannot be concluded that the declaration is commensurate in scope with the claims. Further, since the prior art, as indicated above, discloses the advantages of adding inositol, creatine and arginine in terms of muscle strength and/or growth to protein based supplements, the declarations conclusions, even if valid, are not unexpected.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
Technology Center 1600
March 13, 2008

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616